FORMPTO-1390(Modified) (REV11-98) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: **70869-0068US**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR): **09/623793**

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US99/05287	**11 March 1999 (11.03.99)**	**11 March 1998 (11.03.98)**

TITLE OF INVENTION

Apparatus For The Sterile Transfer of Fluids

APPLICANT(S) FOR DO/EO/US

Wesley H. Verkaart; Lin A. Jakary, legal representative of John R. Wells, deceased; Lou Blasetti

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

Verified Statement Claiming Small Entity Status (37 CFR 1.9(f) and 1.27(c)) - Small Business Concern

U.S. APPLICATION OR PATENT NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/623793	PCT/US99/05287	70869-0068US

21. The following fees are submitted:	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO **$970.00**		
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$840.00**		
☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$690.00**		
☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$670.00**		
☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) **$96.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$690.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	$0.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	13 - 20 =	0	x $18.00	$0.00	
Independent claims	2 - 3 =	0	x $78.00	$0.00	
Multiple Dependent Claims **(check if applicable)**.			☐	$0.00	
TOTAL OF ABOVE CALCULATIONS =				$690.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) **(check if applicable)**.			☒	$345.00	
SUBTOTAL =				$345.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).			+	$0.00	
TOTAL NATIONAL FEE =				$345.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).**			☐	$0.00	
TOTAL FEES ENCLOSED =				$345.00	
				Amount to be: refunded	$
				charged	$

☒ A check in the amount of **$345.00** to cover the above fees is enclosed.

☐ Please charge my Deposit Account No. in the amount of to cover the above fees.
A duplicate copy of this sheet is enclosed.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **50-1088** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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Conrad Clark
SIGNATURE

Conrad J. Clark
NAME

30,340
REGISTRATION NUMBER

September 8, 2000
DATE

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN			Docket No. 70869-0068US
Serial No.	Filing Date Int'l: March 11, 1998	Patent No.	Issue Date

Applicant/ Patentee: **Verkaart, et al.**

Invention: **Apparatus For The Sterile Transfer Of Fluids**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
- ☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: **Harvest Technologies Corporation**

ADDRESS OF CONCERN: **77 Accord Park Drive, D-7, Norwell, Massachusetts 02061, USA**

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:

- ☒ the specification filed herewith with title as listed above.
- ☐ the application identified above.
- ☐ the patent identified above.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ no such person, concern or organization exists.
☐ each such person, concern or organization is listed below.

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: **Wesley H. Verkaart**
TITLE OF PERSON SIGNING OTHER THAN OWNER: **Vice-President**
ADDRESS OF PERSON SIGNING: **77 Accord Park Drive, D-7**
Norwell, Massachusetts 02061

SIGNATURE: Wesley H. Verkaart DATE: 9/5/00

APPARATUS FOR THE STERILE TRANSFER OF FLUIDS

TECHNICAL FIELD

This invention relates to the art of devices used for collecting fluids in a sterile manner while in a non-sterile field, maintaining the sterility of the fluids, and then transferring the fluids so collected to a sterile field. In particular, the invention relates to a syringe for use in collecting and transferring physiological fluids from a non-sterile field to a sterile field.

BACKGROUND

A surgical suite is physically divided between a "sterile field" and a "non-sterile field." The sterile field comprises the patient, the doctors and attending nurses, the equipment required for the procedure, and the physical portion of the suite occupied by this personnel and equipment. While the non-sterile field can be defined broadly as the area not in the sterile field, it is generally considered to comprise the personnel and equipment in an area adjacent the sterile field where tasks directly associated with the surgery are conducted. A problem often confronted during surgery is the maintenance of sterile conditions in the sterile field when passing items from the non-sterile field to the sterile field.

In one technique for passing an article from the non-sterile field to the sterile field, the article is sterilized and brought to the non-sterile field in a container that maintains the sterility. The container is opened by a person in the non-sterile field

without touching the article. The container is then held adjacent the boundary (which may be imaginary) so that the article may be removed from the container by one in the sterile field. This technique is generally satisfactory. A particular problem, however, has been the transfer of sterile fluids to the sterile field.

A known technique for the transfer of fluids to the sterile field includes withdrawing the fluids into a syringe in a known, sterile manner, carrying the syringe of fluid to the boundary of the sterile field, and discharging the fluid from the syringe into a container in the sterile field. Discharge of the fluids into an open container, however, carries the risk that some of the fluids will be spilled and, thus, lost. In some instances, the needle of the syringe is inserted into the port of a container in the sterile field, but this is problematic because these ports are small and hard to engage. Further, the container is often held by a person in the sterile field, and this presents the risk that the needle will inadvertently be brought into contact with the person holding the container. This risks transmission of diseases to the person in the sterile field.

SUMMARY OF THE INVENTION

The method and apparatus of the invention provide collection of fluids in a non-sterile field and efficient, safe transfer of those fluids to the sterile field. While the invention finds particular use in connection with the production of autologous fibrinogen as described in US Patent 5,707,331, it may be used for the transfer of virtually any fluid in a sterile manner. For example, the system of the invention may be used to transfer to a sterile field such fluids as thrombin, cryoprecipitate, and fibrinogen. These materials may, further, be autologous or not.

In accordance with the procedures relating to fibrinogen as described in the noted patent, blood obtained from a patient is treated to remove the fibrinogen, which is then combined with thrombin and applied to the patient as a sealant. Because the equipment for treating the blood is located in the non-sterile field, transfer of the fibrinogen to the sterile field presents a problem to which this invention is addressed.

An apparatus in accordance with the invention comprises a syringe held in an outer casing in such a manner that the syringe can be used for collection of fluids, for example autologous fibrinogen, and then passed to personnel in the sterile field while retaining the casing in non-sterile field. In addition, the casing provides means whereby the plunger in the syringe can be operated repeatedly without compromising sterility.

In the preferred embodiment, the apparatus of the invention includes a syringe removably mounted in a cylindrical outer casing. The casing comprises two main parts, which may be separated to allow a syringe to be inserted and removed. The first part is generally cylindrical and receives the barrel part of the syringe. A second part is detachable from the first part and engages one end of the plunger of the syringe. When the two parts are secured to each other with the syringe therein, the syringe is maintained in a sterile condition. The second part of the casing is flexible whereby the plunger of the syringe may be operated while maintaining the sterility of the syringe. In one embodiment, the second part includes a bellows for allowing the plunger of the syringe to be moved linearly within the syringe barrel while maintaining the sterility of the syringe. In a second embodiment, the second part comprises a highly flexible envelope in the form of a "bag." The length of this envelope is such that it extends from the connection with the first part to the plunger the when the plunger is in an extended

position, as when the syringe is filled. The bag is flexible enough to easily fold over on itself when the plunger is depressed, as in the initial, empty condition.

In a preferred embodiment, the method of the invention includes the steps of drawing material into a sterile syringe held in a casing while in the non-sterile field, opening the casing to expose the syringe and holding the casing such that the syringe can be grasped by a person in the sterile field and removed from the casing, or dropped into the sterile field. Then, the syringe in the sterile field is operated to dispense the material in the sterile field. The material is preferably fibrinogen that has been separated from a patient's blood.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a top view in partial cross section of a first embodiment of an apparatus in accordance with the invention.

Figure 2 is a side view of the apparatus of figure 1 in partial cross section.

Figure 3 is a cross section taken along line 3-3 of figure 2.

Figure 4 is a cross section taken along line 4-4 of figure 2.

Figure 5 is a side view of the apparatus of figure 1 in partial cross section and in an extended position.

Figure 6 is an exploded side view of the apparatus of figure 1.

Figure 7 is a side view of a syringe portion of the invention of figure 1.

Figure 8 is a transverse cross section of a second embodiment of an apparatus in accordance with the invention.

Figure 9 is a bottom view of the connector element of the embodiment of figure 8.

Figure 10 is a vertical cross section of a third embodiment of the invention with the plunger extended.

Figure 11 is a vertical cross section of the third embodiment with the plunger depressed.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to figure 1, a first embodiment of an apparatus in accordance with the invention includes an outer casing 2 for receiving and operating a syringe while maintaining the sterility of the syringe. The casing comprises a first part 4, which receives the barrel portion of the syringe, and a second part 6, which engages the plunger portion of the syringe. The first and second parts are connected to each other to form a receptacle for receiving the syringe, and they may be detached to allow removal of the syringe, as will be described more fully below.

The second part 6 of the casing includes a clamp 12 for releasable attachment to the end of the syringe plunger. This clamp is mounted on a shaft 8 adjacent a base 10 and a thumb knob 14, which receives a user's thumb. One end of a bellows 16 is attached to the outer end of the shaft 8, and the other end of the shaft, having the base 10, is attached to an end 18 of the syringe plunger. The other end of the bellows 16 is attached to a connector 20, which is removable from the first part. The bellows allows the plunger 18 to be moved linearly to draw fluid in or expel fluid from the syringe without loss of sterility of the syringe or the fluid. That is, the bellows is sterilized prior to use and provides a sterile, closed environment in which the plunger moves.

As illustrated, the bellows may be attached to the shaft 8 and the connector 20 by lapping the material of the bellows over a lip on the connector and a disk at the end

of the shaft. Cement may be used to secure the bellows to these elements. Other methods of attachment will be apparent.

The first part includes finger grips 22, which are positioned on the first part to cooperate with the thumb knob 14 to allow a user to grasp the outer casing easily to control movement of the syringe plunger.

In the embodiment shown in figures 1 through 6, the clamp 12 comprises gripping elements 24 and 26 pivotally connected to the shaft 8. For example, central parts of the gripping elements adjacent fulcrum portions may be held to the shaft by a band 28, and the respective tips are urged toward each other by an elastic band 30.

Figure 3 shows the connection between the clamp 12 and the syringe plunger 18. The base 10 has stops 32 and 34 for engaging diametrically opposed parts of the end of the plunger 18, while the clamp elements 24 and 26 grip the end of the plunger at diametrically opposed locations rotationally displaced from those engaged by the stops 32 and 34. It will be appreciated that the stops prevent movement of the end of the plunger in the plane of the base 10 in one direction while the gripping elements 24 and 26 prevent movement in the plane of the base in a transverse direction and also secure the plunger to the base. Thus, the plunger will move linearly with movement of the shaft 8.

Figure 4 illustrates how the flange of the syringe is received in a recess in the first part to secure the syringe rotationally.

Figures 5 through 7 illustrate how the described apparatus can be used in accordance with a method of the invention. A needle 36 is attached to the tip 38 of the first part 4. A syringe includes a barrel 40 and a plunger 18. The barrel is received in a

cylindrical section of the first part 4 and includes a tip 42 that engages the tip 38 of the first part to provide a detachable but fluid-tight seal. Fluid is drawn in to the syringe by inserting the needle into the fluid and withdrawing the plunger, as illustrated in figure 5. A user can do this by inserting fingers in the finger grips 22, a thumb in the thumb knob 14, and pulling the thumb knob outwardly. Because the syringe is contained within the space created by the bellows, the plunger can be moved repeatedly to withdraw and expel the fluid to produce a mixing action.

Then, the casing is opened by detaching the connector 20 from the remainder of the first part while retaining the connection between the syringe and the shaft 8. This will allow the user to remove the syringe from the first part of the casing while touching only the connector, bellows, or thumb knob. Thus, the sterility of the syringe has been maintained. Then, the user can place the syringe into the sterile field by holding the thumb knob. A person in the sterile field can than grasp the syringe while the user releases the clamp elements 12 as shown in figure 6. This release is accomplished by squeezing the clamping elements together through the flexible bellows. The syringe of fluid is then available for use in the sterile field as shown in figure 7.

In the embodiment of figures 1 through 7, the connection between the tip 42 of the syringe and the tip 38 of the first part of the casing is a lap joint. That is, the interior surface of the tip 38 is conical and the exterior surface of tip 42 is conical. These conical surfaces fit closely together to form a seal. Figure 8 illustrates a second embodiment wherein the syringe 40 includes a threaded, male Luer lock connector 44. The outer casing includes a threaded female connector 46 that cooperates with male

connector 44 to securely connect the two elements. These threaded elements are preferably in the form of the Luer connector commonly used in medical equipment.

A male Luer lock connector 50 is provided on the exterior of the first part 4 of the outer casing for removably receiving a needle such as that shown at 36 in figure 5. Such a needle would be provided with a female Luer lock as known in the art.

The embodiment of figure 8 also provides an alternate connection between the thumb knob 14 and the end of the syringe plunger 18. In this embodiment, the plunger 18 is received in a connector 48 such that the plunger may be reciprocated during withdrawal of a fluid into the syringe 40 and detached during transfer of the syringe. With reference to figure 9, it will be appreciated that connector 48 includes a recess 50 for receiving the head 18' of the plunger 18. The plunger shaft is received in a slot 54 in a lower surface 56 of the connector 48.

The slot 54 opens to the side of the connector 48 to allow the head 18' of the plunger to be detached from the connector by sliding the plunger outwardly. The bellows 16 is attached to a side surface of the connector above the slot 54 and is flexible enough to allow the head to be removed from the recess 50 by sliding the plunger along the slot 54.

The end of the bellows 16 that is attached to the first part 4 of the outer casing is resilient and is received in an annular groove in a flange portion 56 of the part 4. The bellows may be detached from the flange by pulling it out of the groove. Preferably, this end of the bellows is provided with a tab for facilitating engagement by the fingers of a user. Alternatively, the end of the bellows is held in the groove by a band that must be removed before detaching the bellows.

Thus, the embodiment shown in figures 8 and 9 is operated much like the first embodiment. That is, the fluid to be transferred is withdrawn into the syringe 40 by moving the thumb knob outward. Then, the bellows is released from the flange 56 and the connector is detached from the plunger. These steps are accomplished with the user holding the outer casing in one hand and the thumb knob or bellows in the other and without touching the syringe. After exposing the syringe, the user extends it into the sterile filed, whereupon one in the sterile field releases it from the Luer lock and removes the syringe. Alternatively, the user releases the syringe from the Luer lock by engaging the syringe through the bellows and twisting it. The bellows is then removed, and the syringe allowed to slide from the casing and onto a receiving surface in the sterile field.

The embodiment of figures 10 and 11 is preferred because of its ease of manufacture. According to this embodiment, the first part of the outer casing is a rigid or semi-rigid tube 58 with a closed end fitted with internal and external Luer connectors 60 and 62, respectively. Preferably, the length of the tube 58 is such that its upper end 64 lies slightly below the finger flanges 66 of the syringe barrel 40.

The tube 58 is preferably made of transparent or highly translucent plastic, such as polycarbonate, polyester, polyethylene, polypropylene, styrene, acrylic, or similar materials.

The second part of the outer casing in this embodiment comprises a thin, flexible envelope 68. This envelope is in the form of a highly flexible bag sealed on three sides and open at one end. The open end fits over the finger tabs 66 and over the outside diameter of the rigid tube 58. The length of the bag is such that it completely encloses

the plunger, finger flanges, and upper part of the rigid tube 58. The bag is preferably made of transparent plastic, such as polyethylene film, with a thickness of 1 to 4 mils.

The open end of the bag 68 is secured to the tube 58 with an air-tight seal strip 70. The seal strip includes a pull tab 72 that facilitates grasping by the user for removal of the seal strip and release of the envelope 68 from the tube 58.

The seal strip may be adhesive-backed tape, perforated tape, an elastic strip, or a shrink-wrapped strip. The pull tab 72 may be colored to contrast with the remainder of the strip for easy location by the user.

A retainer 74 may be placed at the upper end of the envelope to hold it to the plunger to facilitate the user's grasping the plunger. The retainer may be a flexible plastic clip in the form of a horseshoe, an elastic o-ring, or the like, that is easily removed from the bag and plunger during transfer of the syringe to the sterile field. The retainer may be of any of a variety of materials, such as nylon, rubber, and the like.

Figure 11 illustrates the syringe with the plunger in the empty position. The envelope is fully collapsed in this condition. In the condition shown in figure 11, there is a given amount of air in the envelope. As the plunger is withdrawn, the air contained in the syringe barrel is expelled into the envelope so that there is no necessity for air to enter or leave the envelope during motion of the plunger. This absence of venting assists in ensuring maintenance of sterility.

The operation of the embodiment shown in figures 10 and 11 is the same as that illustrated in figures 5 through 7. That is, a needle 36 is attached to the connector 62, and the plunger 18 is withdrawn to draw fluid into the syringe. Then, the seal strip 70 is removed, and the syringe removed from the tube 58 by twisting to disengage the Luer

or other lock 60, with the user holding the syringe by the plunger through the envelope 68. Then, the tube is handed to a second user in the sterile field and the envelope is released from the plunger by detaching the retainer 74. Another technique would be to release the retainer and seal strip, grasp the plunger through the envelope in one hand and the tube 58 in the other, twist the two to release the lock 60, and then remove the envelope. The syringe can then be presented to a second user in the sterile field for removal from the tube 58. Or the envelope can be removed and the syringe presented to the second user, who twists the syringe to release the lock and remove it from the tube.

It will be appreciated that selected features of each of the embodiments shown may be employed in the other embodiment. Thus, the Luer connectors of the embodiment of figures 8 and 9 may be used in the embodiment of figures 1 through 7.

The articles described herein are preferably made of plastic and may be manufactured with any of a variety of techniques, including, for example, injection molding, blow molding, extrusion and other known techniques.

Modifications within the scope of the appended claims will be apparent to those of skill in the art.

We Claim:

1. Apparatus for transferring a fluid to a sterile field comprising a first part and a second part separable from said first part, wherein said first part includes a cavity adapted to receive a first part of a syringe and allows communication with said syringe from outside said cavity, and said second part is adapted to receive a second part of said syringe.
2. Apparatus according to claim 1 wherein said first part is adapted to receive a barrel portion of said syringe and said second part is adapted to receive the plunger part of said syringe.
3. Apparatus according to claim 2 wherein said first part is a rigid tube and said second part is flexible.
4. Apparatus according to claim 3 wherein said second part is a bellows.
5. Apparatus according to claim 3 wherein said second part is a thin flexible sheet.
6. Apparatus according to claim 5 wherein said thin flexible sheet is in the form of a bag.
7. Apparatus according to claim 2 wherein said first part is adapted to receive only part of said barrel and said second part is adapted to receive said plunger and a part of said barrel.
8. Apparatus according to claim 2 wherein said second part comprises means for releasable engagement of said plunger.
9. Apparatus according to claim 8 wherein said means for releasable engagement comprises a clip.

10. Apparatus according to claim 8 wherein said means for releasable engagement comprises a disc with a slot for receiving an end of said plunger.

11. A method for transferring a fluid to a sterile field comprising the steps of providing a syringe in a two part enclosure that allows operation of said syringe while in said enclosure, operating said syringe to draw said fluid into said syringe, separating said two part enclosure to expose said syringe while engaging only said enclosure, and passing said syringe to said sterile field.

12. A method according to claim 11 wherein said step of passing comprises dropping said syringe onto a receiving surface in said sterile field.

13. A method according to claim 11 wherein said step of passing comprises handing said syringe to a user in said sterile field.

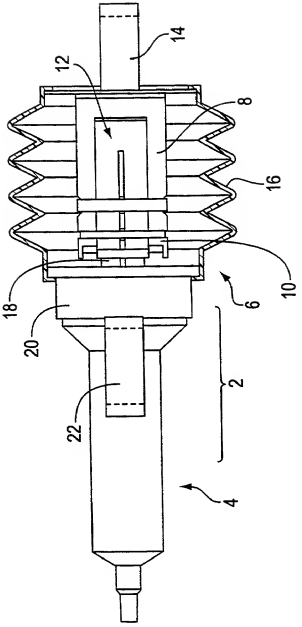

FIG. 1

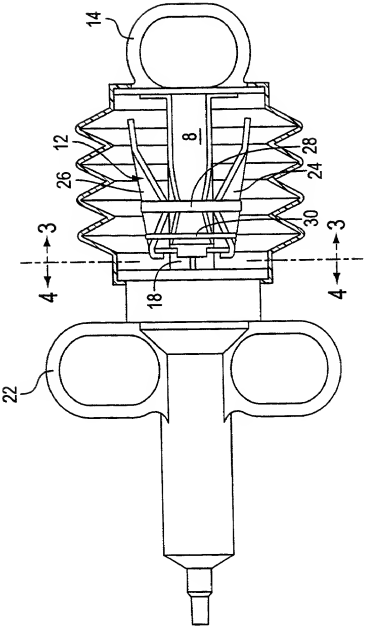

FIG. 2

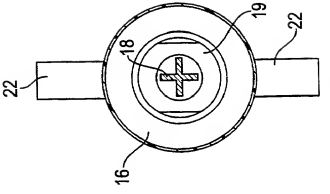

FIG. 4

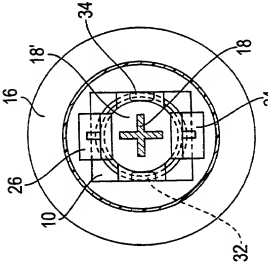

FIG. 3

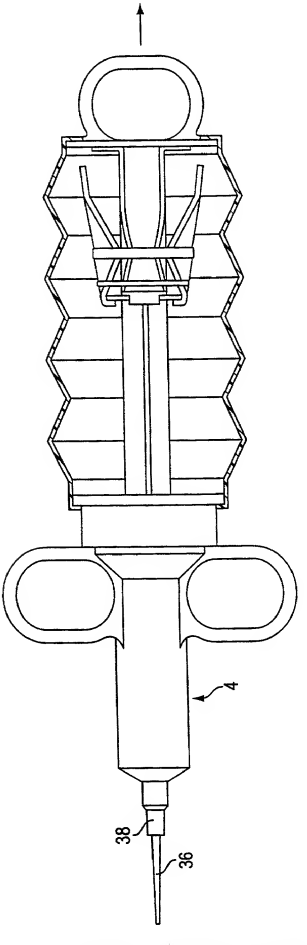

FIG. 5

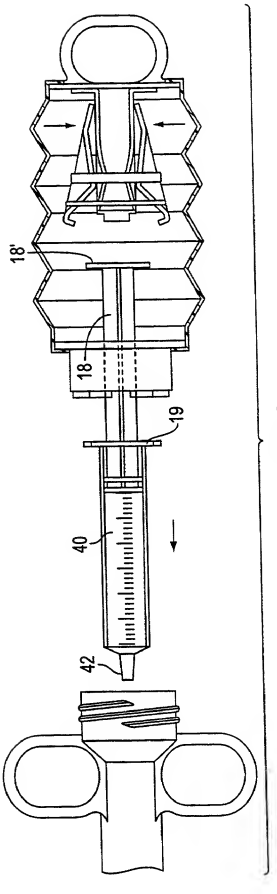

FIG. 6

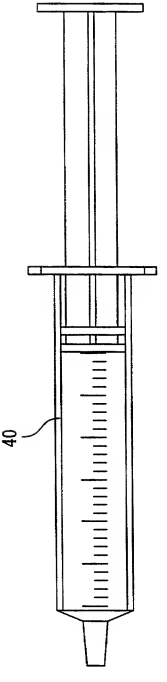

FIG. 7

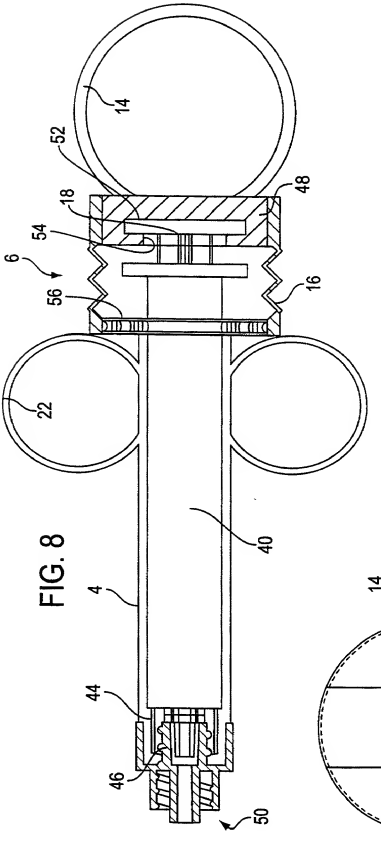

FIG. 8

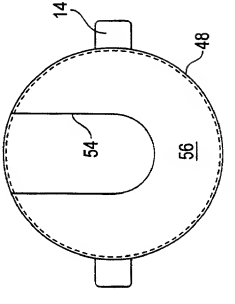

FIG. 9

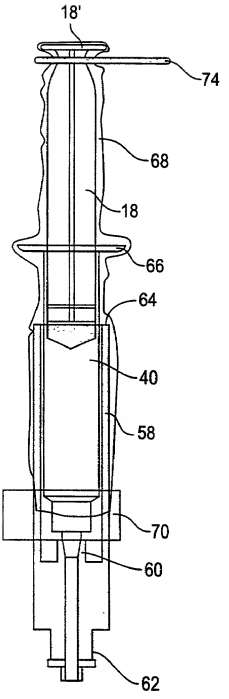

FIG. 10

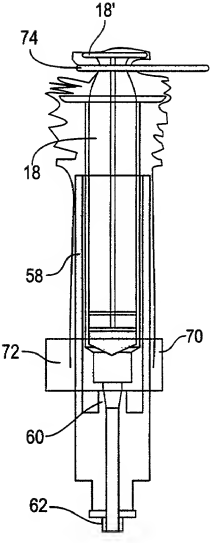

FIG. 11

Docket No.: 70869-0068US

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I declare that:

My residence, post office address, and citizenship are as stated below next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled

Apparatus For The Sterile Transfer Of Fluids

☐ the specification of which is attached hereto.
☒ was filed on **March 11, 1999** as International Patent Application No. **PCT/US99/05287** and was filed as National Stage U.S. Patent Application No. **09/623,793** on September 8, 2000.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information of which I am aware and which is material to the examination of the patent application in accordance with 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designates at least one country other than the United States, listed below and have also identified below, by checking the space, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is not claimed.

Prior Foreign Application(s)

Number	Country	Day/Month/Year Filed	Priority Not Claimed

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

Application Serial Number	Filing Date

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s), or §365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information known to me which is material to the patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Application Serial Number	Filing Date	Status (patented, pending, abandoned)
PCT/US99/05287	11 March 1998	inactive

Each undersigned applicant hereby appoints **CONRAD J. CLARK (Registration No. 30,340)** and **CHRISTOPHER W. BRODY (Registration No. 33,613)** as his attorneys with full power of substitution to prosecute the subject application and to transact all business in the Patent and Trademark Office connected therewith.

Send Correspondence to: **CLARK & BRODY, 1750 K Street, NW, Suite 600, Washington, DC 20006; Telephone: 202-835-1111; Facsimile: 202-835-1755.**

I hereby declare that all statements made herein of my own knowledge are true and that all statement made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1 of 2

Full name of sole or first inventor: Wesley H. Verkaart
Inventor's signature: Wesley H. Verkaart Date: 8/24/01
Residence: Duxbury, Massachusetts 02332
Citizenship: United States
Post Office Address: 15 Hounds Ditch Lane, Duxbury, Massachusetts 02332

Full name of second joint inventor, if any:	Lin A. Jakary, legal representative of John R. Wells, deceased	John R. Wells
Residence:	La Jolla, California	La Jolla, California
Citizenship:	United States	United States
Post Office Address:	551 Gravilla Street, La Jolla, California 92037	6509 Avenue Mayana, La Jolla, CA 92037

Signature of Legal representative for inventor, John R. Wells: Date:

2 of 2

Full name of third joint inventor, if any: Lou Blasetti
Inventor's signature: Lou Blasetti Date: 8-24-01
Residence: North Quincy, Massachusetts
Citizenship: United States
Post Office Address: 11 Ketch Lane, North Quincy, Massachusetts 02171

X Fourth and subsequent joint inventors are listed on second sheet

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Inventor's signature: _____ Date: _____
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Citizenship: United States
Post Office Address: 15 Hounds Ditch Lane, Duxbury, Massachusetts 02332

Full name of second joint inventor, if any: Lin A. Jakary, legal representative of John R. Wells, deceased — John R. Wells
Residence: La Jolla, California CA — La Jolla, California
Citizenship: United States — United States
Post Office Address: 551 Gravilla Street, La Jolla, California 92037 — 6509 Avenue Mañana, La Jolla, CA 92037
Signature of Legal representative for inventor, John R. Wells: _____ Date: Aug 23, 2001

Full name of third joint inventor, if any: Lou Blasetti
Inventor's signature: _____ Date: _____
Residence: North Quincy, Massachusetts
Citizenship: United States
Post Office Address: 11 Ketch Lane, North Quincy, Massachusetts 02171

x Fourth and subsequent joint inventors are listed on second sheet

Full name of fourth inventor: Steven M. Gann

Inventor's signature: _____ Date: _____

Residence: Huntington Beach, California

Citizenship: US

Post Office Address: 912 Delaware, Huntington Beach, California 92648

Docket No.: 70869-0068US

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Signature of Legal representative for Inventor, John R. Wells: _____ Date: _____

Full name of third joint inventor, if any: Lou Blaselli
Inventor's signature: _____ Date: _____
Residence: North Quincy, Massachusetts
Citizenship: United States
Post Office Address: 11 Ketch Lane, North Quincy, Massachusetts 02171

_x_ Fourth and subsequent joint inventors are listed on second sheet

Full name of fourth inventor: Steven M. Gann

Inventor's signature: _____ Date: _____

Residence: Huntington Beach, California

Citizenship: US

Post Office Address: 912 Delaware, Huntington Beach, California 92648

Docket No. 70869-0068 US
U.S. Serial No. 09/623,793

Full name of fourth inventor: Steven M. Gann
Inventor's signature: Date: 8/15/2001
Residence: Huntington Beach, California CA
Citizenship: US
Post Office Address: 912 Delaware, Huntington Beach, California 92648